



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/400,817	09/22/1999	JAMES P. KOCH	01996/005001	3842

26161 7590 09/25/2003

FISH & RICHARDSON PC  
225 FRANKLIN ST  
BOSTON, MA 02110

EXAMINER

BROWN, MICHAEL A

ART UNIT	PAPER NUMBER
----------	--------------

3764

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/400817

Applicant(s)

James P. Koch

Examiner

Michael Brown

Group Art Unit

3264

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-3, 5-6, 8-17, 19-36, 39-50 and 57-59 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 28-32 and 57 is/are allowed.
- ☒ Claim(s) 1-3, 5-6, 8-17, 20-25, 27, 33-36, 39-48 and 58-59 is/are rejected.
- ☒ Claim(s) 19, 26 and 49-50 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 3764

### DETAILED ACTION

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 6, 10-11, 44-46 and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipfert in view of Goepp.

Lipfert discloses in figures 1-3 a cervical cap comprising a rim member (30, 44) dimensioned to snugly fit a patient's cervix (since the exocervix is a part of the cervix, the rim member fits the exocervix also), a cap dome 20, a valve 56 that includes a membrane 58 made of a polymer (silicone) disposed over an outer surface of the dome and sealed to the cap dome in space regions (fig.2) and the rim includes circumferential ridges (the notches 36 provide ridges) on its inner surface. However, Lipfert does not disclose the cap dome being made of a cured polymeric material or the cap dome being custom made. Goepp teaches in figures 1 a custom made cap dome comprising a rim 35 that permits a snug fit between rim 35 and the exocervix (col. 4, lines 65-69 and (col 6, lines 1-6). The cap dome is made of a cured polymeric material (ethylene-butylene rubber). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the cap dome as disclosed by Lipfert could be fabricated on a cured polymeric material as taught by Goepp because it is a material that prevents sperm from reaching the cervix. The teaching of having a rim that snugly fits the exocervix is clearly

Art Unit: 3764

provided by Goepp, as set forth above. The valve could be a collapsed elastomeric tube (col. 6, lines 36-37) as disclosed by Lipfert.

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 2 above, and further in view of Cox.

Cox teaches in figure 1 a cervical pessary comprising a valve that is a duckbill valve 26 (see attached sheet at the end of the patent). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the duckbill valve as taught by Cox could be substituted for the valve as disclosed by Lipfert because either valve could be used to release fluids from the body, yet prevent sperm from entering the cap.

4. Claims 8-9, 12-13, 15, 17, 20, 22-25, 27, 41-43 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipfert in view of Goepp, along with Shields.

Lipfert discloses in figures 1-2 a cervical cap, as set forth above. Goepp teaches in figures 1-2 a cervical cap, as set forth above. However, neither reference discloses a portion of the cap impregnated or coated with a therapeutic agent. Shields teaches in figures 1-2 a cervical cap comprising a portion 72 having a therapeutic agent (Nonoxynol-9) impregnated into the portion. The agent is released over a period of time (through openings 42). The function of the therapeutic agent was not given patentable weight (note claim 22). Shield teaches a ring 14 that is removable (not complete away from the cervical cap but removable away enough to allow the portion with the therapeutic agent to be removed. It is inherent that the membrane could be any desired thickness.

Art Unit: 3764

***Claim Rejections - 35 U.S.C. § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 33-36, 39-40 and 51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goepp.

7. Claims 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims above, and further in view of Petrus.

Petrus teaches a cervical cap (col. 1, lines 25-27) and an iodine that may be dissolved in a spermicide (col. 6, lines 27-29). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the iodine as taught by Petrus could be incorporated into the cervical cap as disclosed by Lipfert and taught by Goepp and Shields in order to use the iodine as an anti-inflammatory medicament in the cervix.

***Allowable Subject Matter***

8. Claims 19, 26 and 49-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3764

9. Claims 28-32 and 57 are allowed.

*Conclusion*

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. No additional prior art was cited during this office action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is (703) 308-2682.

M. Brown  
September 22, 2003

A handwritten signature in black ink that reads "Michael A. Brown". The signature is written in a cursive, flowing style.

Michael A. Brown  
Primary Examiner